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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
CHAPMAN, GINGER T	

ART UNIT	PAPER NUMBER
3761	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/623,316	CHILDERS ET AL.	
	Examiner	Art Unit	
	Ginger T. Chapman	3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 November 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-61* is/are pending in the application.

4a) Of the above claim(s) *27-61* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7,10-14,16-21 and 24-26* is/are rejected.

7)☒ Claim(s) *8,9,15,22 and 23* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *04 April 2007* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/05/2008*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the claims

1. Claims 1-61 are pending in the application; claim 20 is amended; claims 27-61 are withdrawn from consideration as being drawn to a nonelected invention.

Information Disclosure Statement

2. The information disclosure statement (IDS) submitted on November 5, 2008 was filed after the mailing date of the non-final rejection on August 19, 2009. The submission is in compliance with the provisions of 37 CFR §§ 1.97 and 1.99. Accordingly, the information disclosure statement is being considered by the examiner.

3. See citation of pertinent art under the heading "Conclusion" *infra*.

Response to Arguments

4. Applicant's arguments, see Remarks, p. 1, filed November 6, 2008, with respect to the rejection of claim 1 under 35 USC 102(b) as anticipated by Roberts et al (US 5,944,684) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Roberts ('684) in view of Savitz et al (4,229,299).

5. With respect to the dependent claims, Applicants' arguments are addressed in the rejections of the claims below.

Allowable Subject Matter

6. The indicated allowability of claims 15 and 22 is withdrawn in view of the newly discovered reference(s) to Polaschegg et al (US 4,702,829) and Laroche et al (US 2005/0102028 A1). Rejections based on the newly cited reference(s) follow.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. Claims 1-4, 6, 7, 10, 12, 14, 16, 17-19 and 24-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Roberts (US 5,944,684) in view of Savitz et al (US 4,229,299).

10. With respect to claim 1, as best depicted in Figure 2, Roberts discloses a system for providing dialysis comprising: a patient fluid loop (c. 7, ll. 55-60) including a first pump 8a and a

second pump 8c; and multiple patient lumens (c. 8, l. 7); a second fluid loop; a membrane device 10 in fluid contact with and separating the patient fluid loop and the second fluid loop, the membrane device 10 allowing at least one selected component of the fluid in the patient fluid loop to transfer to the second fluid loop (c. 6, ll. 12-13 and c. 3, ll. 40-50);the second loop being closed except for the transfer of the selected component via the membrane device 10 (c. 8, ll. 55-57; c. 6, ll. 49-50; fig. 2); and a controller that operates the first 8a and second 8c pumps to recirculate fluid in the patient loop and the second loop (c. 8, ll. 2-5).

11. Roberts discloses the claimed invention except for a medical fluid regenerator and a second pump which is included in the second fluid loop. As best depicted in Figure 1, Savitz teaches a second fluid loop including a pump 116 and a medical fluid regenerator 123 (c. 5, ll. 40-47). Savitz teaches that this allows spent dialysate to be re-freshed into fresh dialysate and recirculated through the system thus providing motivation for such. Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system of Roberts as taught by Savitz since Savitz states, at c. 5, ll. 32-46 and c. 3, ll. 39-40, that the benefit of such a modification is that it permits recirculation of the dialysate while returning waste impurity-depleted blood to be returned to the patient.

12. With respect to claim 2, Roberts discloses the membrane device 10 is a dialyzer (c. 5, ll. 66-67 to c. 6, ll. 1-2).

13. With respect to claim 3, Roberts discloses a pressure gradient exists across a membrane device (c. 6, l. 33; c. 4, l. 14).

14. With respect to claim 4, Roberts discloses the patient loop is closed except for the transfer of the selected component via the membrane device (c. 7, ll. 25-30).

15. With respect to claim 5, Roberts discloses the claimed invention except expressly disclosing the membrane device includes a nanofilter. Roberts, at c. 3, ll. 10-15, teaches the filter having a suitable pore size to separate the dialysate into ultrafiltrate and protein-containing fractions, thus providing motivation to select a filter size for the desired component and intended use. Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the membrane device of Roberts with the claimed size filter since it would be within the general skill of a worker in the art to select a known size filter on the basis of its suitability for the intended use. Additionally, all filters perform the substantially identical function in the substantially identical manner, i.e. separating out selected matter or particles or other material by passing liquid or gas through a porous mass is a well-known function of essentially all filtering devices; the Federal Circuit has held that, where the only difference between the prior art and the claims was a recitation of relative dimensions of the claimed device and a device having the claimed relative dimensions would not perform differently than the prior art device, the claimed device was not patentably distinct from the prior art device. *Gardner v. TEC Systems, Inc.*, 725 F.2d 1338, 220 USPQ 777 (Fed. Cir. 1984), *cert denied*, 469 U.S. 830, 225 USPQ 232 (1984).

16. With respect to claim 6, Roberts discloses the medical fluid regenerator includes a uremic toxin sorbent (c. 8, l. 51-52; c. 3, ll. 41-45).

17. With respect to claim 7, Roberts discloses the medical fluid regenerator includes at least one of: urease, zirconium phosphate, zirconium oxide and carbon (c. 3, ll. 45-50; c. 6, ll. 15-20).

18. With respect to claim 10, Roberts discloses the claimed invention except a gas separator. Savitz teaches a dialysis system comprising a vent to selectively vent accumulated air from

chambers 46 and 64. Therefore it would have been obvious ton one having ordinary skill in the art at the time the invention was made to provide the system of Roberts with a vent as taught by Savitz in order to prevent gas from being returned with the blood to the patient's body.

19. With respect to claim 11, Roberts discloses the claimed invention except for a multi-analyst sensor. Savitz teaches multi-analyte sensor 105. Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to include a multi-analyte sensor is the system of Roberts as taught by Savitz since Savitz teaches, at c. 6, ll. 40-54, that the benefit of such is that it permits monitoring of electrolytes in the dialysis fluid to insure the dialysate solution has the proper level of salinity and electrolytic characteristics so that vital components of the blood are not lost the dialysate solution by ion diffusion, thereby providing a safer dialysis system.

20. With respect to claim 12, Roberts discloses peritoneal dialysis fluid is circulated through the patient fluid loop (c. 7, ll. 54-55).

21. With respect to claim 13, Roberts discloses the claimed invention except for blood is circulated through the patient fluid loop. Savitz, at c. 4, l. 46, teaches a hemodialysis system thereby providing motivation for such; in hemodialysis blood is circulated through the patient fluid loop. Therefore it would have been obvious to modify the system of Roberts as taught by Savitz since it is known in the art that dialysis systems can comprise peritoneal, haemofiltration and hemodialysis systems and the selection of either system for a particular patient would be an obvious modification of the treatment made by the treating physician on a case-by-case basis.

22. With respect to claim 14, Roberts discloses at least parts of the patient fluid loop and the second fluid loop are provided in a disposable device (c. 3, ll. 50-52 and ll. 61-62; c. 7, ll. 29-31).

23. With respect to claim 16, Roberts discloses the controller enables fluid flow in opposite directions through the multiple patient lumens (c. 8, ll. 7-9).

24. With respect to claim 17, Roberts discloses a dual lumen catheter (c. 8, ll. 7-8).

25. With respect to claims 18 and 19, Roberts discloses the claimed invention except for in-line fluid heaters comprising a radiant heater and a plate heater. Savitz, teaches in-line 129 fluid heaters 103, 152; and teaches at c. 12, ll. 28-30 that the heaters selected may be of any suitable type for the purpose of maintaining the dialysate solution at ~ normal body temperature. Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the system of Roberts with heaters of any suitable type as taught by Savitz since Savitz states, at c. 6, ll. 10-15, that the benefit of such a modification is that it prevents undue cooling or heating of the blood in contact with the dialysate and to prevent hemolysis thereby providing a safer dialysis system.

26. With respect to claim 24, as best depicted in Figure 2, Roberts teaches an ultrafiltrate container 11 in fluid communication with at least one of the patient and second fluid loops (c. 7, ll. 58-60).

27. With respect to claim 25, Roberts discloses a fluid concentrate container 12 in fluid communication with at least one of the patient and second fluid loops (c. 7, ll. 60-61).

28. With respect to claim 26, Roberts discloses a controller operates the first pump 8a continuously to pump fluid into and out of a patient (c. 8, ll. 7-11).

29. Claims 8 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Roberts in view of Savitz and further in view of Kawaguchi (US 2003/0000876 A1).

30. With respect to claim 8, the combination of Roberts and Savitz disclose the claimed invention except for a gas separator that removes gas from at least one of the patient and second fluid loops. As best depicted in Figure 1, Kawaguchi teaches a gas separator 66 that removes gas from a second fluid loop. Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to form the system of Roberts/ Savitz including a gas separator as taught by Kawaguchi, since Kawaguchi states, at [0032] that the benefit of including a separator is that it removes gas from the supply of dialysate fluid.

31. With respect to claim 9, Roberts in combination with Savitz disclose the claimed invention except for the gas separator and medical fluid regenerator are provided in a single device. As best depicted in Figure 1, Kawaguchi teaches a gas separator for removing fluid from a dialysate fluid supply. The gas separator of Kawaguchi is included in a second fluid loop which supplies dialysate fluid into the system, therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made that the gas separator of Kawaguchi could be integrated with other components in the loop including a medical fluid regenerator and to provide the components within a single device, since both are provided in the same loop and it is known in the art to integrate components and therefore is an obvious modification.

32. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Roberts in view of Savitz and further in view of Polaschegg et al (US 4,702,829).

33. With respect to claim 15, the combination of Roberts and Savitz disclose the claimed invention except for the second fluid loop includes a balance chamber. As best depicted in Figure 1, Polaschegg teaches a dialysis system including balance chambers 30, 70. therefore it would have been obvious to one having ordinary skill in the art at the time the invention was

made to included balance chambers as taught by Polaschegg in the system of Roberts/ Savitz, since Polaschegg teaches at c. 4, ll. 52-59, that the benefit of providing balance chambers is that it ensures proper balance of incoming and outgoing fluids by providing predetermined quantities of fluid to enter and exit the system thereby balancing the fluids to reduce risks to a patient and providing a safer dialysis sytem.

34. Claims 20-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Roberts in view of Savitz and further in view of Krivitski et al (US 5,685,989).

35. With respect to claims 20-21, Roberts in view of Savitz discloses the claimed invention except for optical, fluid volume and capacitance sensors. Krivitski provides clear motivation for optical sensors at c. 2, ll. 11-12. Krivitski, at c. 4, ll. 24-27, teaches that optical, fluid volume and impedance, i.e. capacitance, sensors are known to measure change of characteristics of blood flow through dialysis loops. Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to select any of these known sensors to obtain the benefits of blood monitoring that Krivitski discloses thereby providing a safer dialysis system.

36. Claims 22 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Roberts in view of Savitz and further in view of Laroche et al (US 2005/0102028 A1).

37. With respect to claims 22 and 23, Roberts in view of Savitz discloses the claimed invention except for capacitance sensors. As best depicted in Figure 1, Laroche teaches capacitance sensors 18, 22 to measure pressure within a chamber and the chamber is a pump 14 chamber as recited in claim 23. Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was to include capacitance sensors as taught by Larocke in the chambers and system of Roberts/ Savitz since Laroche teaches their suitability for use in

dialysis and extra-corporeal blood circulation systems and capacitance sensors are known in the art to measure pressure within chambers and pressure within a chamber is proportionate to volume of fluids or gases within a chamber and therefore could be used to measure and monitor pressure and volume within a chamber.

38. With respect to claim 8, the prior art teaches gas separators to remove gas from untreated water that enters a dialysis system as make-up water for preparing dialysis solution. The prior art does not teach or fairly suggest removing gas from patient or dialysate fluid loops because water does not circulate in the patient fluid loop and one would not be motivated to provide a gas separator is the dialysate fluid loop because the water used for the dialysate has just been deaerated and there would be no need for further deaeration.

Conclusion

39. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

40. Wamsiedler et al (US 6,042,784), submitted as a third-party submission in a published application under 37 CFR § 1.99, relates to a system for providing dialysis, in particular for accurately determining the volume of ultrafiltrate and dialysate fluids used and discarded in hemodiafiltration and replacing spent fluids such that the volume of ultrafiltrate is balanced against a volume of substituate used in the system. The system utilizes a volumetric balancing chamber being subdivided into two chambers by a moveable partition, the moveable partition comprising a displaceable membrane.

41. Wamsiedler teaches that spent ultrafiltrate fluid and dialysis fluid used in the system may be diverted into a drain, and may also be diverted to a drip chamber to be supplied to the patient. Wamsiedler does not teach a medical fluid regenerator or sorbent means that regenerate or reuse spent dialysate. Wamsiedler teaches that spent dialysate is sent to the ultrafiltrate balancing chamber, spent ultrafiltrate and dialysis fluid are removed from the chamber and removed from the system, i.e. is diverted to the drain means at a rate of about one-tenth of the dialysate flow per cycle of the balance chamber; fresh dialysate fluid is supplied from a dialysate reservoir.

42. The system of Wamsiedler is of the type discussed in the instant Specification at ¶¶ [0013] wherein spent dialysate is sent to a drain or collected in a drain bag. The instant Specification discloses that an object of the instant invention is to reduce the amount of dialysate which is discarded during dialysis by regenerating the spent dialysate fluid into fresh dialysate by through sorbents to remove toxins thereby permitting the dialysate to be recirculated through the system and thereby reducing costs to patients, reducing the requirement of patients to acquire and store large amounts of dialysate thereby and providing more economical and convenient dialysis systems for the patients.

43. Wamsiedler teaches balancing chambers, however, absent evidence to the contrary, it appears one of ordinary skill in the art at the time of invention would not be motivated to modify the instant invention as taught by Wamsiedler or to combine the system and balancing chamber of Wamsiedler with the instant system because the object of Wamsiedler is to remove spent fluids, replace these quantities of spent fluids and to accurately determine the volume of removed fluids. Because an object of the present invention is to conserve and reuse dialysate and not to remove and replace the fluid, it appears that the object of Wamsiedler would be frustrated.

44. Cappelen, Jr (US 3,528,550) teaches removing air from tap water before it enters a dialysis system, and removing gas from a degasser upstream of a dialysis apparatus by utilizing fluid flow and fluid pressure of fluid that has already left the dialysis device. '550 at c. 1, ll. 59-60, "to ensure that the dialysis liquid is air free when entering the dialysis apparatus proper", at ll. 60-65: "this is achieved by passing the dialysis liquid, upon having been passed through the dialysis apparatus, and through a venturi device which, by means of a conduit, is connected to a degassing device for the liquid positioned upstream of the dialysis apparatus." at c. 2, ll. 1-4, the liquid flow will, as in a water jet pump, draw air from the degassing device so that the liquid when arriving at the dialysis apparatus will be air and gas free,"

45. Figures 1 depicts that tap water is fed from water tap 1, into valve 2, then split into 2 streams, one stream goes into heater 3, the other into mixing valve 4, then both streams are fed into degasser 5. After leaving degasser 5, the water goes through pump 6, conduit 8, then is mixed with dialysis liquid concentrate from tank 10 to form a dialysate solution, the solution is then fed into tank 11, and from tank 11 dialysate fluid then enters the dialysis apparatus 14.

46. Dialysis apparatus 14 is shown as a black box with no loops and no structure is disclosed for the dialysis apparatus itself. Spent dialysate then leaves the dialysis system 14, and is drawn through connection 15 by the suction of pump 16 which is downstream of the dialysis apparatus, Venturi device 17 is between connection 15 and the pump 16, Venturi device does not draw fluid from the dialysis machine 14, the venturi device draws air previously removed from the tap water, said air drawn directly from the degasser 5 through conduit 18 which bypasses the dialysis device and connects directly to the venturi device 17. The flow of fluid from the dialysis machine is what goes into the venturi device and the pressure of the fluid flow draws air from the

degasser. Venturi devices are known to use combinations of narrow and wide constrictions within a fluid flow conduit to increase (or decrease) fluid flow and thereby increase or decrease pressure within the conduit. The used dialysis fluid from the dialysis apparatus 14 along with air removed from the tap water by the degasser 5 through conduit 18 by means of the increased pressure created in the venturi 17 is then drained at 19. The liquid with absorbed gases is a combination of the liquid previously degassed before it enters the dialysis machine and the absorbed gasses are from degasser 5 which gas has never entered the dialysis system so was never removed from either of the fluid loops in the dialysis system.

47. It appears that the degasser does not have a vent to off-gas the air, and '550 suggests that the degasser is closed, so the collected air never enters the dialysis machine and bypasses the dialysis machine and is then off-gassed directly from the tap water by means of using the pressure of dialysis fluid leaving the system to "suck" the air out of the de-gasser and then into conduit 18 then into the pump and drain. The fluid is drained, and not re-introduced into the dialysis machine.

48. It appears that the system of '550 is the same system that paragraph 32 above teaches is prior art, but '550 does not appear to teach removing gas from any fluid loops in a dialysis machine, it appears to teach removing air from tap water before it reaches a dialysis machine, then using the dialysis fluid leaving the machine to drain the air, such that the gas is removed both before and after it reaches a dialysis machine, but the degasser never actually removes air/gas from fluid in the fluid loops in the machine:

49.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ginger T. Chapman whose telephone number is (571)272-4934. The examiner can normally be reached on Monday through Friday 9:30 a.m. to 6:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on (571) 272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ginger T Chapman/
Examiner, Art Unit 3761
01/16/08

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